

REMARKS/ARGUMENTS

Reconsideration of the application is respectfully requested.

1) Claims 34 – 36 and 45 are rejected under 35 U.S.C. §102(e) as being anticipated by Lindqvist et al. (6,051,747). Applicant respectfully traverses this rejection.

The Examiner states in the Office Action that Lindqvist et al. disclose a wound dressing comprising three layers, a first gel layer 3, a second polyurethane foam layer 2, and a third liquid-impervious layer 5 on a side of the dressing opposite the side of the dressing having the gel layer 3, and that "The gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the wound, excess wound fluid can be drawn into the foam material 2 and absorbed thereby."

Applicant had previously pointed out that the Lindqvist foam layer (an intermediate layer) does not have a foam layer which contacts the wound surface. Rather, the gel layer is disclosed to contact the surface, not the foam layer.

The Examiner in the instant Office Action contends that the current claim language includes "comprising" and asserts that this language does not exclude additional layers such as Lindqvist's gel layer. However, if that is the case, then there is not a layer on the other side of the foam that is the Applicant's membrane layer. Rather, the Office Action appears to be considering the foam and gel of Lindqvist to be "a layer". Assuming that is the case, then, there still is not a layer (e.g., a foam layer as claimed by Applicant) that would constitute the second layer that would be used for contacting the wound to provide a surface of a second disparate wound healing characteristic.

Second, assuming the construction advanced in the Office Action, if the second wound

contacting side is considered to be formed of the Lindqvist foam and gel, and Lindqvist's foam is "the second layer" of this second wound contacting side that forms the second wound contacting side of the composite structure, then since a liquid impervious layer (5) (in addition to the foam and gel layers) is provided on the opposite side of the gel layer (see col. 2, lines 64-66), then there is still not a second layer which is a foam layer that provides a disparate wound healing characteristic (i.e., different than the first layer or gel layer). Therefore, there is not, in Lindqvist, Applicant's claimed foam layer, the second layer, which is a foam layer, where that second layer forms the second wound contacting side of the composite structure. Taking the Office Action, and viewing what Lindqvist discloses, a water impervious layer (5), and not the absorbent foam (2), would be on the other side (or forming one side of the Lindqvist dressing). (The other side being the gel layer.)

Even considering the claims, as previously presented, the Applicant's invention is not anticipated by Lindqvist. However, Applicant has amended claim 34 to more particularly distinguish the invention by reciting the foam layer or second layer is designed to contact the wound:

a second layer forming the second wound contacting side of the composite structure, the second layer being a foam layer arranged in said composite structure to contact a wound when said second wound contacting side is the side facing said wound.

The above amendment more particularly distinguishes the invention, even over what the Office Action considers Lindqvist to disclose.

Claim 34, as now amended, and claims 35, 36, and 45, which depend from Applicant's claim 34, should be patentable over Lindqvist for the above reasons. Further, the dependent claims add additional claim elements which further define Applicant's invention over the cited

reference.

2) Claims 34, 36, 40, and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Hofeditz (4,552,138). Applicant respectfully traverses this rejection.

As Applicant previously pointed out, unlike Applicant's invention recited in Applicant's claim 34, Hofeditz does not disclose a dual-purpose wound dressing having **both** a membrane layer as a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side.

Applicant further pointed out that although Hofeditz has a gel layer having an outer wound contacting surface, Hofeditz, in contrast to Applicant's invention, has a foam layer which is not, as Applicant recites and claims, a wound contacting layer which is:

a second layer forming the second wound contacting side of the composite structure, the second layer being a foam layer arranged in said composite structure to contact a wound when said second wound contacting side is the side facing said wound.

Hofeditz does not disclose a foam layer having an outer wound contacting surface having wound healing characteristics, as called for by Applicant's claim 34.

The Examiner, in the current Office Action, has responded to the Applicant's position, namely, stating that Hofeditz discloses a gel layer that is the membrane layer (considering the membrane to be defined as a "thin, soft pliable sheet or layer" and a polyurethane foam layer). The Examiner considers the Hofeditz wound dressing to be useable "upside down". This statement alone is a recognition that the Office Action understands Hofeditz to have a correct side (e.g., "right-side up" versus "upside down").

If one of ordinary skill in the art were to follow the teachings of Hofeditz, one would not arrive at the Applicant's present invention, but rather something else. Hofeditz fairly discloses that the foam would be one of the other supporting or absorbent materials as an intermediate layer. Therefore, one desiring two wound contacting surfaces would not have gained this teaching from Hofeditz. Assuming one were to consider the Hofeditz disclosure and attempt even to gain from it two wound treating surfaces (which Hofeditz does not disclose or suggest), one of ordinary skill in the art, at best would therefore use two gel surfaces if one were to use Hofeditz's teachings (as Hofeditz does not teach use of two wound contacting surfaces in the first place, let alone two surfaces each with disparate wound healing properties).

Moreover, according to Hofeditz, the covering layer is not disclosed to be the foam layer, but rather a layer that covers the surface of the gel layer. Accordingly, Hofeditz would be understood by one of ordinary skill in the art that the reference to intermediary layer and to covering layer, is a reference that the foam is an intermediary layer, and that the covering layer is what Hofeditz says it is – namely, a protective film which may be impermeable to water vapor anchored onto the gel. (See col. 2, lines 59-62) The covering layer would be just that, *a cover for the gel*. That is not the same as an intermediate layer, which would mean then that the polyfoam layer (not disclosed to be a protective film covering layer) but rather an intermediate layer, would not provide a surface for wound contact or treatment, but would be disclosed to be intermediate (i.e., between other layers).

Hofeditz's disclosure does not teach, suggest or disclose the Applicant's invention.

Accordingly, withdrawal of the rejection of claim 34 is respectfully requested.

Applicant's claims 36, 40, and 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define

Applicant's invention over the cited reference.

3) Claims 34 – 36, 38, 42 – 43, and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Freeman (5,681,579). Applicant respectfully traverses this rejection.

As Applicant previously pointed out, Freeman, does not disclose a dual-purpose wound dressing having **both** a membrane layer as a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side.

Unlike the Applicant's invention, Freeman discloses various wound dressings comprising a polymeric support layer and an occlusive backing layer overlaying the support layer. Typically, an adhesive layer is applied to the outer face of the support layer, or to the inner surface of an overhanging portion of the occlusive backing layer, for adhering the dressing to the skin of a patient. Freeman's occlusive backing layer does not have an outer wound contacting surface having wound healing characteristics, as called for in Applicant's claim 34.

One of ordinary skill in the art looking at Freeman would not have arrived at the Applicant's claimed invention.

The Office Action contends that Freeman discloses a "polymeric membrane layer (12) and a "polyurethane foam layer (11)". However, what Freeman discloses is an "occlusive layer 11" and a "polymeric support layer 12". Applicant has reviewed Freeman, and the response to Applicant's arguments presented in the instant Office Action.

The rejection in the Office Action is based on Freeman allegedly disclosing a dressing with an outer surface of layer 12 that contacts the wound, an inner surface of layer 11 that contacts the wound (also when the outer surface of layer 12 is contacting

the wound) and an outer surface 14 of layer 11 that the Office Action contends is a layer that contacts the wound.

Applicant's invention is distinguishable over Freeman. First, the Office Action, on page 10, in support of the rejection, contends that Freeman's overhang portion of layer 11 (referring to Fig. 1), would contact the wound (citing to col. 4, lines 13-15). However, the surface disclosed to be in contact with skin in Freeman is not a *wound contacting surface that has wound healing characteristics* as disclosed and claimed by Applicant, but rather is adhesive. Freeman discloses this at col. 4, line 65- col. 5, line 1:

As seen in FIG. 1, the dressing is in an island form where there is adhesive material that is not covered by polymeric support layer 12 and which can be used to adhere the dressing to the patient.
(Freeman, col. 4, line 65 – col. 5, line 1)

Accordingly, what is disclosed to one of ordinary skill in the art looking to Freeman is that adhesive is the surface contacting the skin, and not what the Office Action considers to be the foam layer. In addition, Applicant's claims refer to and claim two different sides of the wound dressing providing the disparate healing characteristics, and include language in the claims stating -- *depending on which side of the wound dressing contacts the wound* (see claim 34). Considering what the Office Action rejection relies on in Freeman's disclosure of Fig. 1, the side contacting the wound would be the same side, and not, as Applicant claims, separate sides.

Second, considering the basis for the rejection that the outer surface 14 of the layer 11 would contact the wound, there is no disclosure in Freeman supporting that contention. In fact, according to Freeman, it is not disclosed to be a wound healing

layer or as a surface which is applied to a wound and that has wound healing properties. Rather, whatever the surface disclosed in Freeman, for the Freeman dressing to be operative, it is disclosed to be “open to the atmosphere” (see Freeman, col. 4, lines 13-14). One of ordinary skill in the art would not understand this to be a wound healing surface of a dressing as disclosed by Freeman. Again, Freeman does not disclose that a second side of its dressing would have wound healing characteristics.

According to the Office Action if one considers what is actually disclosed in Freeman, there would not be a choice of a disparate surface to apply. Freeman does not disclose discrete surface applications for a wound, e.g., such as a membrane surface healing characteristics versus Applicant’s recited foam surface healing characteristics, since Freeman, according to what is disclosed, would provide both of the surfaces referred to in the Office Action to the wound at the same time. See Fig. 1 and see surface of layer 12 and surface 13.

The Freeman reference does not disclose or suggest the Applicant’s claimed invention.

In addition, Freeman appears to disclose that the web or net (layer 12) is of the order of about 0.5 to 2 to 3 millimeters thick. Applicant’s membrane layer is a thin layer of 50 microns in Applicant’s Example 1 (and see claim 44). This is another reason why one of ordinary skill in the art would not be led by Freeman’s disclosure to arrive at the present invention.

Freeman fails to suggest or disclose the Applicant’s present invention.

Reconsideration and a withdrawal of the rejection is respectfully solicited.

Applicant's claims 35, 36, 38, 42-43, and 45 depend from Applicant's claim 34 and are patentable for the same reasons. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

4) Claims 37 and 39 – 42 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lindqvist et al. (6,015,747) in view of Lorenz et al. (5,258,421) and as evidenced by US Patent 4,832,009. Applicant respectfully traverses this rejection.

Applicant has previously pointed out that none of the cited references teaches or suggests, either alone or in combination, Applicant's dual-purpose wound dressing having a **first wound contacting side** having an outer wound contacting surface that has wound healing characteristics and a **second wound contacting side** having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side of the composite structure. Applicant argued that neither Lindqvist nor Lorenz nor US Patent No. 4,832,009 discloses a wound dressing having both a first wound contacting side having an outer wound contacting surface having wound healing characteristics and a second wound contacting side having an outer wound contacting surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side.

The Office Action considered the Applicant's arguments, but has presented further statements against the Applicant's position.

First, as Applicant has pointed out above, Lindqvist does not disclose or suggest the Applicant's claimed invention, and the present invention is distinguishable over Lindqvist. For the above reasons, even the further combination of Lorenz and US 4,832,009, applied with Lindqvist, do not render the present invention obvious.

Second, on page 12 of the Office Action, the rejection is based on the cited references allegedly disclosing and teaching that the use of polyurethane film and silicone PTFE IPN function in a similar manner, referring to them as “functional equivalents”. However, this statement would support the patentability of Applicant’s claimed invention, in particular, that the dressing provides, not equivalent, but disparate wound healing properties (depending on which surface of the first side or second side surfaces is applied to the wound). Since the Applicant claims a membrane and a foam layer, and further that Applicant discloses that the foam may be polyurethane foam, the applied teachings of the references, as asserted in the Office Action, do not teach, suggest or disclose the present invention, since applying those teachings would be inconsistent, as the polyurethane polymer is disclosed to be polyurethane foam according to the Applicant’s invention, and the membrane the silicone containing polymer. Contrary to the Office Action, one of ordinary skill in the art cannot read the disclosures of the references to arrive at the Applicant’s claimed invention.

Taking the alleged teachings that the Office Action credits the references with providing, and applying them, would not result in an understanding to use a silicone containing composition (i.e., Applicant’s silicone IPN, a silicone PTFE IPN). It would follow that if one were to replace polyurethane with silicone containing layers, then there is the potential to have two silicone layers, not a polyurethane foam layer, since the teachings allegedly are credited in the Office Action with replacing such composed layers (e.g., the polyurethane layer) with silicone containing layers. For these additional reasons, the proposed combination of references would not have been obvious, nor would it have resulted in the Applicant’s claimed invention, even if attempted.

Claim 41 is not obvious for the above reason and for additional reasons. As Applicant previously pointed out, the pigmented adhesive layer recited in claim 41 provides a visual indicator for differentiating one side of the dressing from the other side of the dressing in the field. Applicant has amended claim 41 to more particularly distinguish the invention by referring to the orienting indicator being provided. Claim 41, as amended, now recites:

the adhesive layer containing a orienting indicator for orienting a side of a surface to a wound, said orienting indicator being provided in the form of a pigment for imparting a discernable color to the adhesive layer that may be seen through the first layer of the wound dressing.

None of the references provides an orienting indicator, nor accomplishes it by providing pigment in the adhesive connecting a translucent layer to an opaque layer to distinguish one side of the dressing from the other side of the dressing.

5) Claim 44 is rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lindqvist et al. (6,015,747) by itself or in view of Freeman (5,681,579). Applicant respectfully traverses this rejection.

For the reasons set forth above distinguishing the present invention over Lindqvist, the Applicant's invention, as recited in claim 44, is not obvious, even when the further reference of Freeman is applied. In addition, for the above reasons, Freeman also fails to disclose or suggest the invention, alone or when proposed to be combined with Lindqvist.

6) Claims 37, and 39-41 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz et al. (5,258,421) and as evidenced by US Patent No. 4,832,009. Applicant respectfully traverses this rejection.

First, for the reasons set forth above, Applicant submits that the references fail to suggest or disclose the Applicant's present invention. The present invention is distinguishable over

Freeman and Lorenz, as discussed above.

The rejection above attempts to rely on Lorenz et al. for its alleged disclosure of silicone PTFE. However, reliance on a silicone containing release liner (which is designed to be removed for use of the dressing) would not render the present invention obvious.

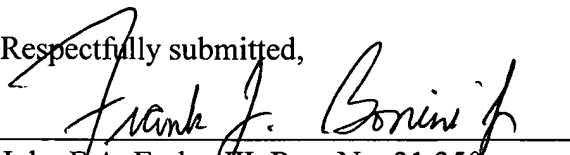
In addition, it would follow that if one were to replace polyurethane with silicone containing layers, then there is the potential to have two silicone layers, not a polyurethane foam layer, since the teachings allegedly are credited in the Office Action with replacing such composed layers (e.g., the polyurethane layer) with silicone containing layers. The Applicant's foam layer is a polyurethane layer. If the teaching relied on is to replace a polyurethane layer with a silicone IPN, then two silicone IPN layers would result. For the above reasons, and for these additional reasons, the proposed combination of references would not have been obvious, nor would it have resulted in the Applicant's claimed invention, even if attempted.

For the above reasons, and for these additional reasons, the rejections should be withdrawn.

If necessary, an appropriate extension of time to respond is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required to Patent Office Deposit Account No. 05-0208.

Respectfully submitted,

A handwritten signature in cursive script, reading "Frank J. Bonini, Jr.", is written over a horizontal line.

John F.A. Earley III, Reg. No. 31,350

Frank J. Bonini, Jr., Reg. No. 35,452

Charles L. Riddle, Reg. No. 54,779

Harding, Earley, Follmer & Frailey

Attorneys for Applicant

P.O. Box 750

Valley Forge, PA 19482-0750

Telephone: 610-935-2300

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